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PATENT--NO FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

ANIL GULATI

Serial No.: 10/691,915

Filed: October 23, 2003

For: **METHOD AND COMPOSITION FOR PREVENTING AND TREATING SOLID TUMORS**

Attorney Docket No. 27611/38802A

Group Art Unit: 1642

Examiner: Brandon J. Fetterolf, Ph.D.

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage, as first class mail, in an envelope addressed to: Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dated: April 7, 2005

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RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Office Action dated March 8, 2005, applicants hereby elect the invention represented by the claims of examiner's Group I, namely, claims 1-13, with traverse, for examination on the merits at this time. Applicants also elect, with traverse, the endothelin agonist identified as BQ123. Applicants further elect, with traverse, a breast tumor as the tumor, and paclitaxel as the chemotherapeutic agent. It is submitted, however, that all endothelin

agonists should be examined at this time. The novelty of the invention is use of an endothelin agonist in the treatment of a solid tumor. Individual endothelin agonists are not independent and distinct inventions because the statutory requirements of 35 U.S.C. §121, namely, independence and distinctness, are not present herein.

The individual endothelin agonists are not independent inventions because the endothelin agonists set forth in the claims are so closely related that a search for applicants' elected endothelin agonist would necessarily encompass a search for the remaining endothelin agonists.

In addition, even if individual endothelin agonists are considered independent inventions, there is no evidence that a search and examination directed to endothelin agonists in general would be a *serious burden* on the examiner, as is required by M.P.E.P. §803. ("If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." and "There must be a serious burden on the examiner if restriction is not required.")

In particular, it is submitted that a complete search directed to applicant's elected endothelin agonist would require a search directed to endothelin agonists in general, and vice versa.

Because search and examination of all endothelin agonists can be made without serious burden on the examiner, it would be wasteful of the time, effort,

and resources of both the applicants and the Patent Office to prosecute each endothelin agonist in separate applications. Search and examination of all endothelin agonists in a single application would be much more efficient than requiring the Patent Office to prosecute each endothelin agonist in separate applications. Search and examination of all endothelin agonists of claims in a single application would be much more efficient than requiring the Patent Office and applicants to do so in separate applications. Accordingly, it is submitted that all endothelin agonists should be examined at this time.

With respect to the election of a single tumor, the claims recite a solid tumor, and as such, these tumors are sufficiently related such that the search could be expanded, without a serious burden, to encompass solid tumors in general, as opposed to solely breast tumors.

Likewise, the election of a single chemotherapeutic agent is unduly restrictive. The treatment involves diagnosis of a solid tumor and treatment using a chemotherapeutic agent effective for treating the tumor. The administration of an endothelin agonist potentiates the chemotherapeutic effect, and this effect is independent of the chemotherapeutic agent. Accordingly, it is submitted that all chemotherapeutic agents should be examined at this time.

Reconsideration and withdrawal of the restriction requirement are respectfully requested. An early action on the merits is solicited.

Respectfully submitted,

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April 7, 2005